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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,922	04/30/2001	Masayuki Fukumura	4001-0003CIP	2336

7590 05/18/2005

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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/843,922	**Applicant(s)** FUKUMURA ET AL.	
	Examiner Robert M. Kelly	**Art Unit** 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☒ Newly proposed or amended claim(s) *17-18* would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *16-18*.
   Claim(s) objected to: *none*.
   Claim(s) rejected: *1-4,6-11 and 16-21*.
   Claim(s) withdrawn from consideration: *none*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 12/2/04
13. ☒ Other: See Continuation Sheet.

Continuation of 5. Applicant's reply has overcome the following rejection(s): The provisional rejections of the claims based on the 09/720,003; 09/720,979 are overcome by the amendments and allowance of 09/720,003 and the abandonment of 09/720,979. The rejections of claims 9-10 and 16 based on written description are overcome by Applicant's proposed amendments to the claims and arguments. The enablement rejections of claims 1-4, 6-11, and 16-21 are overcome on all bases, except the treatment of any animal.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's methods claims remain rejected under 35 USC 112, first paragraph, for lacking an enabling disclosure, because they embrace in vivo methods for any animal, because the rejection limits Applicant to treatment of rodents only, and applicant's arguments fail to overcome that aspect of the rejection. To wit, Applicant argues that the vectors are fully enabled for the treatment of any neurodegenerative condition, such as, for example, Parkinson's disease, ischemia, and the like (Applicant's response of 4/13/05, p. 20, last paragraph). From this, it is clear that Applicant believes the claims to encompass the treatment of any disease, particularly in humans, as Parkinson's disease is a human disease. However, as was stated in the prior official Actions, the amount and duration of gene expression in enough cells for a long enough period of time is critical, and specific, for the specific disease being treated (e.g., Official Action of 5/5/04, p. 19, paragraph 2) and also such treatment is not reasonably predictable to be efficacious in other animals, including humans, when success is seen in mice (Id., p. 18, paragraph 1). Hence, Applicant's showing in mice and gerbils is persuasive for rodents, it does not reasonably demonstrate reasonable predictability for other animals, such as humans. This is compounded by the fact that each disease requires different transgenes, levels of expression, and durations of expression (Id., p. 19, paragraph 2). Hence, extrapolating Applicant's showing of treating ischemic disease in rodents to treating Parkinson's disease in humans is not reasonably predictable. Applicant submits an article: Glorioso, et al. (2003) J. NeuroVirology, 9: 165-72 to argue that in vitro data reasonably correlates to in vivo data (Applicant's argument of 4/13/05, p. 21, paragraph 1). Glorioso teaches that particular vectors, none of which are sendai vectors, may be useful for the treatment of particular diseases (p. 169, col. 2, paragraph 2); however, Glorioso does not teach a clear correlation between the treatment of small animals and larger mammals, including humans. For example, while treatment of mice with 6-OHDA was successful for at least one behavioral abnormality, Glorioso recognizes that the complexity of the disease in humans makes similar treatment unpredictable (Glorioso, p. 166, col. 2, paragraph 2). Also, Glorioso is post filing evidence, and at Applicant's filing date these same problems also existed. Although multiple specific vectors have been shown with limited outcomes in small animals by Glorioso, no where does Glorioso teach expolation to any animal, much less humans, from the results obtained in such small animals. Moreover, while reviewing adenoviral, adenoassociated viral, lentiviral, and herpes simplex viral vectors, it is clear that each specific vector is specific for a particular type of disease (Id.). Hence, while addressing particular vectors, Glorioso does not address sendai vectors, and evidences that each vector is particular to a particular type of disease, which means that Glorioso does not enable Applicant's broadly claimed methods for any animal, which is compounded further by any disease. With regard to the provisional double-patenting rejections, Applicant has indicated a desire to file a terminal disclaimer for the two applications that are still at issue, after the filing of the after-final amendment, but has not done so, and therefore, the provisional rejection of claim 16 remains.

Continuation of 13. Other: Applicant's IDS of 12/2/04 has been considered and signed; however, the Examiner has crossed through all of the citations, as they can not be printed on the face of any patent that might issue, because the Artisan could not find such references.

DAVE TRONG NGUYEN
PRIMARY EXAMINER